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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,999	02/29/2000	Yoshihiro Tanimoto	KODA20A.001AUS	1582

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**Application No.  
**09/514,999**Applicant(s)  
**Tanimoto et al.**Examiner  
**Irene Marx**Art Unit  
**1651**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Apr 25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-9 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Since this application is eligible as a Continued Prosecution Application under 37 CFR 1.153(d), the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.153(b). Applicant's submission filed on 4/25/02 has been entered. Claims 2-9 are being considered on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation "for a time period effective to increase a yield of polyamines recovered in a subsequent recovery step by approximately two times or more" as now recited in claim 9. In the specification, at page 10, lines 24 et seq. it is indicated that with the specific procedure of Example 3 it was possible to obtain a yield 3.2 times more than the yield of polyamine composition obtained by a conventional method. The material used is a commercial yeast RNA.

It must be noted that the claim as written has an infinite upper limit and does not indicate how the comparison is intended to be achieved. Also there is no clear correlation between the claim designated "polyamines" obtained by various alternative means in claim 9, and the "polyamines" obtained by a specific method from a specific source recited in the cited passage from the specification.

Also, the requisite time period to obtain a yield of more than 3.2 times in yield of polyamines is not disclosed in the as-filed specification.

Therefore, this material raises the issue of new matter and should be deleted.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that the upper limit is not important and that one of ordinary skill in the art can readily practice the claimed invention without an indication of the upper limit. However, insertion of the limitation "for a time period effective to increase a yield of polyamines recovered in a subsequent step by approximately two times or more" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the way of obtaining "approximately two times or more", i.e., an increase of more than 3.2 times. There is only exemplification of a yield of polyamines of up to 3.2. This is not sufficient support for the new genus having no upper limit. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the concept. If it does not, the material is new matter. Thus, the insertion of "approximately two times or more" is considered to be the insertion of new matter because specification shows how to obtain an increase in yield of 2 times, 3 times and 3.2 times but does not provide an adequate written description of how to obtain more than 3.2 times.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is confusing in the recitation "a time period effective to increase a yield of polyamines recovered in a subsequent recovery step by approximately two times or more", even when reading the claim in light of the specification, since the requisite time period for more than 3.2 times in yield of polyamines is not disclosed in the as-filed specification. See also the new

matter rejection *supra*. In addition, the intended meaning of "a yield" is unclear. Is there more than one "yield"? Amendment to "the yield would be remedial.

Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an increase in yield of 2-3.2 times whenever decomposition is effected with nuclease A, ribonuclease A + trypsin or 0.3N NaOH on specific polyamine compositions, does not reasonably provide enablement for an increase in yield of more than 3.2 times using any nuclease or alkali and using any yeast somatic components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

From the record of the present written disclosure, applicants have shown how to obtain an increase in yield of 2-3.2 times in the yield of polyamines using decomposition nuclease A, ribonuclease A + trypsin or 0.3N NaOH on specific polyamine compositions, such as RNA compositions. However, applicants have not provided sufficient information to enable one of ordinary skill in the art to achieve increases beyond that amount.

Applicants baldly assert that the upper limit is not important and one of ordinary skill in the art can readily practice the invention without an indication of the upper limit. Yet there is nothing in the as-filed specification regarding procedures and protocols to achieve an increase to 10%, 20% or 50% of the yield using the same or other nucleases or alkali and providing other yeast somatic component preparations.

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

No claim is allowed.

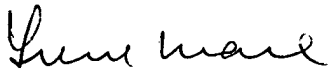
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

  
Irene Marx  
Primary Examiner  
Art Unit 1651